

## AMDR Summary: International Regulation of “Single-Use” Medical Device Reprocessing

Since 2000, the United States Food and Drug Administration (FDA) has regulated reprocessors of so-called “single-use” medical devices (SUDs) as medical device manufacturers, subjecting all reprocessors (third-party, hospital, and original equipment manufacturers (OEMs)) to all of the agency’s medical device manufacturer requirements. Thus, FDA’s regulatory framework for reprocessing is perhaps the longest-standing, most comprehensive in the world. However, the U.S. is not the only nation to address the reprocessing of SUDs. This summary outlines, to the best of AMDR’s knowledge, the legal and regulatory status of SUD reprocessing in a number of jurisdictions, including the European Union (EU), Australia, Canada, South Korea, Saudi Arabia, and Israel.

The reprocessing of SUDs is commonplace worldwide. Even in developed nations, including those that have reprocessing prohibitions in place, hospitals routinely reuse SUDs. Unless otherwise noted below, the available evidence indicates that the reuse of SUDs in most other nations is unregulated. In many cases (particularly in Africa and Asia), uncontrolled reuse of such devices is relatively common, if not the norm.<sup>1</sup>

### EUROPEAN UNION

Currently, the EU does not have a declaration regarding reprocessing of medical devices. However, it is in the process of revising its Medical Device Directive. The European Parliament identified reprocessing of SUDs as an issue in need of additional clarification, and a European Commission report highlighting the risks of unregulated reprocessing was released in August, 2010.<sup>2</sup> We note that original equipment manufacturers are lobbying aggressively for an EU-wide ban on reprocessed devices. Specifically, Eucomed submitted a white paper to the European Commission on reprocessing that alleges patient safety issues associated with hospital reprocessing and recommends that the EU prohibit reprocessing of SUDs.

Currently, regulation of reprocessing activities is left to the individual Member States. Since 2001, Germany has had in place a regulatory framework that does not distinguish between the reprocessing of “reusable” and so-called “single-use” medical devices. The guidelines, therefore, allow for SUD reprocessing if conformance with certain standards is achieved. The

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<sup>2</sup> Report from the Commission to the European Parliament and the Council: [Report on the Issue of the Reprocessing of Medical Devices in the European Union, in Accordance with Article 12a of Directive 93/42/EEC](#), **European Commission** (August 27, 2010) [hereinafter, Commission Report].

German Medical Devices Law and the Medical Devices Operator Ordinance regulate the reprocessing of medical devices and in doing so refer to the mutual recommendation by the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) for the reprocessing of medical devices.<sup>3</sup> As a result, the RKI’s requirements must be observed.

Institutions, which want to reprocess so-called single-use medical devices, must adopt and implement a quality management system according to DIN EN ISO 13485:2007.<sup>4</sup> Compliance with the quality management requirements is monitored annually by “Notified Bodies” that have been accredited by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG).

AMDR is aware that other nations, like Denmark and Sweden, allow for SUD reprocessing under a high quality standard, based on certain governmental records.<sup>5</sup> Other Member States, such as the United Kingdom, Spain and France,<sup>6</sup> discourage or prohibit SUD reprocessing. However, AMDR is aware that, despite these prohibitions or discouragements, reprocessing at the hospital level still occurs.<sup>7</sup> Finally, the majority of Member States in Europe do not have any national regulations regarding reprocessing.<sup>8</sup>

Should the EU revise its Medical Device Directive to address reprocessing, Member States would be obliged to revise their regulations on reprocessing to ensure conformance with the EU requirements.

### **AUSTRALIA / New Zealand**

Australia enacted regulations regarding the reprocessing (“remanufacturing” in Australia) of SUDs in 2003.<sup>9</sup> Similar to the U.S., in Australia, all reprocessors (third-party, hospital, and OEM) must conform to medical device manufacturer requirements as regulated by the Therapeutic Goods Administration (TGA). Prior to implementation of these requirements, hospital reprocessing of SUDs was common. Also like in the U.S., AMDR understands that due to the costs and high technical standards required to meet the TGA’s conformity assessment requirements, hospitals have ceased reprocessing SUDs in-house. In New Zealand, the Regulator Medsafe requires either compliance with the US 510(k), CE approval or a listing with

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<sup>3</sup> *Hygienic Requirements for Processing of Medical Devices: Recommendation by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal German Institute for Medical Drugs and Medical Products (BfArM) Concerning the “Hygienic Requirements for Processing of Medical Devices,” Robert Koch Institute: Recommendation* (2001).

<sup>4</sup> *Id.*

<sup>5</sup> Sundhedsstyrelsen (August 25, 1999) (Denmark) and Medical Devices Act SFS1993: 584 (Sweden).

<sup>6</sup> **Commission Report**, *supra* note 2, at 6. *See also*, Circulaire DGS/DH n 51 (December 29, 1994) *Relative a l’utilisation des dispositifs medicaux steriles a usage unique dans les etablissements de sante publics et prives* (France), Ministerio de sanidad y consume, *Royal Decree 414.1996 Sec. 5*, (July 9, 1999) (Spain) and MHRA Device Bulletin: DB 2006(04) *Single-Use Medical Devices: Implications and Consequences of Reuse* (UK).

<sup>7</sup> *See, e.g., Why a Prohibition of Reprocessing Is a Threat to Patient Safety*” Dr. Jose Fereres, Madrid. EAMDR Tours France (April 2006).

<sup>8</sup> **Commission Report**, *supra* note 2, at 6. *See also*, [European Association of Medical Device Reprocessors](#).

<sup>9</sup> [Statement by the TGA on regulations for sterilisation of single use devices](#), Australian Government, Therapeutic Goods Administration (July 21, 2003).

the Australian TGA for the sale of medical devices within the country. Besides a notification procedure, no further regulatory approval is required.

## **CANADA**

Health Canada does not currently regulate the reprocessing of medical devices at the federal level. Moreover, the Canadian Food Drug and Cosmetics Act and Canadian Medical Device Regulations do not address the way in which healthcare facilities use, maintain or sterilize medical devices. Nevertheless, the practice of reprocessing is thought to be common. Reprocessing issues in Canada have historically been left to the territorial and provincial health ministries and hospital boards.<sup>10</sup>

The following four provinces and territories have undertaken the regulation of reprocessing:

### **British Columbia**

British Columbia issued a policy to its health authorities stating that by January 1, 2008, all health authorities must have eliminated the reprocessing and reuse of critical contact SUDs, unless they have been reprocessed by a licensed third-party reprocessor that is certified by a national regulatory authority such as Health Canada or the U.S. Food and Drug Administration.<sup>11</sup>

### **Manitoba**

Since 1999, Manitoba has not permitted its hospitals to reuse “critical contact” SUDs (*i.e.*, those that contact the bloodstream or a sterile body cavity).<sup>12</sup>

### **Northwest Territories**

Since 2005, the Northwest Territories have prohibited reprocessing. Specifically, the Northwest Territories Department of Health and Social Services revised its *Hospital and Health Care Facility Standards Regulations* to require that “a disposable device intended to be used on a patient during a single procedure shall not be used on a patient for more than one procedure and shall not be used on another patient.”<sup>13</sup>

### **Ontario**

In 2006, the Ontario Ministry of Health and Long Term Care endorsed a guidance document developed by its Provincial Infectious Diseases Advisory Committee (PIDAC) advising that

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<sup>10</sup> *Issue Analysis Summary: The Reuse of Single-Use Medical Devices* **Health Canada; Therapeutic Products Directorate** (April 28, 2005). See also, [Reprocessing Single-Use Medical Devices: An Update of the Clinical Evidence and An Environmental Scan of Policies in Canada](#), **Canadian Agency for Drugs and Technologies in Health** (June 23, 2010).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

critical and semi-critical SUDs must not be reprocessed and reused, unless the reprocessing is done by a licensed reprocessor.<sup>14</sup>

## **ASIA**

The reuse of SUDs in much of Asia is common, particularly for injection needles.<sup>15</sup> For the most part, there are no national regulations governing reuse of SUDs and, thus, third-party reprocessors do not offer their services in Asia. Rather, most reuse in Asia is conducted in an unregulated-manner at the user-facility level.

### **Japan**

Reprocessing is not currently regulated in Japan, but, available data indicates that the reuse of SUDs is relatively common. A 2003 survey found that 80 to 90 percent of hospitals reused SUDs.<sup>16</sup> AMDR is aware of no known quality standards governing such reuse.

### **South Korea**

To the best of our knowledge, South Korea does not regulate reprocessing of medical devices. South Korea’s move toward device regulation in general started with the Medical Devices Act (MDA), which went into effect May 30, 2004, but was not fully implemented until March 30, 2007. Prior to the enactment of the MDA, reprocessing was a topic that was anticipated to be included in that legislation.<sup>17</sup> However, it does not appear that provisions concerning reprocessing ultimately were enacted. AMDR has met with South Korean officials twice in the last several years, indicating that governmental interest in enacting a regulatory framework may still exist.

### **India**

There are no known regulations regarding reuse of medical devices in India. According to information obtained by AMDR, hospitals in India do routinely reuse SUDs. While private hospitals may have guidelines regarding SUD reuse, the processes are not regulated by the government.

## **AFRICA AND THE MIDDLE EAST**

The lack of resources, including medical devices and distribution channels, “necessitates the reuse of single-use devices” in much of Africa.<sup>18</sup> This includes the reuse of syringes and needles that have not been sterilized, and even rubber gloves. In the Middle East, available data indicates that reuse of SUDs is common throughout Arab countries (particularly for cardiac

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<sup>14</sup> *Id.*

<sup>15</sup> **Journal of Hygiene Report**, *supra* note 1, at 304.

<sup>16</sup> *Id.*, at 305.

<sup>17</sup> [Medical Device Regulatory Requirements for South Korea](#), U.S. International Trade Administration (December 20, 2005).

<sup>18</sup> **Journal of Hygiene Report**, *supra* note 1, at 305.

catheters), despite the absence of a regulatory framework. Reprocessing in both Africa and the Middle East is done at the user-facility level.<sup>19</sup>

### **Israel**

Israel does not have regulations in place specific to the reprocessing of SUDs, but as a general matter, medical devices must be registered with the Ministry of Health (MOH) before they can be sold in the country. If a product is approved by the U.S. FDA, it will generally be registered by the MOH with no further testing requirements and, therefore, may be lawfully marketed in the country. Consistent with this policy, AMDR is aware that FDA-cleared reprocessed devices have been registered with MOH and are actively imported into the country.<sup>20</sup>

Of note, as with many other countries, hospitals in Israel are reusing many types of SUDs without any federal oversight or controls. AMDR understands a “Medical Devices Bill” currently under consideration may recommend regulations for reprocessing.<sup>21</sup>

### **Saudi Arabia**

The Kingdom of Saudi Arabia (KSA) has recently taken steps to establish a medical device regulatory structure. The Saudi Food and Drug Authority (SFDA) published an Interim Regulation concerning medical devices on December 27, 2008, which went into effect on March 27, 2009.<sup>22</sup> The Interim Regulation will apply until a comprehensive medical device law is approved.<sup>23</sup>

The Interim Regulation provides that devices may be marketed in Saudi Arabia if they:

“Comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use.”<sup>24</sup>

The devices reprocessed by AMDR’s members comply with the regulatory requirements in the United States. Moreover, there does not appear to be a reprocessing-specific provision included in the Interim Regulation. As such, importing reprocessed devices into the KSA appears to be permissible. However, the SFDA website includes an “information page” that describes an SUD

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<sup>19</sup> **Journal of Hygiene Report**, *supra* note 1, at 305.

<sup>20</sup> [Medical Device Regulatory Requirements for Israel](#), U.S. International Trade Administration (May 2, 2005).

<sup>21</sup> [Reuse of Single-Use Medical Devices, Annual Report 55B](#), pp. 553-565, Israeli State Comptroller, Ministry of Health.

<sup>22</sup> [The Medical Devices Interim Regulation](#), Saudi Food and Drug Authority (April 10, 2010).

<sup>23</sup> *Id.*

<sup>24</sup> [Medical Devices Interim Regulation](#), Report issued by the Saudi Food and Drug Authority Board of Directors, Medical Devices Sector (April 17, 2009).

as “intended for use once, on an individual patient for a single procedure.”<sup>25</sup> This information page goes on to state that an SUD “should not be reprocessed or reused on another patient.”<sup>26</sup> Thus, it appears as though the SFDA has adopted an informal policy that prohibits reprocessing.

Like South Korea, AMDR has had interactions with Saudi Arabian officials, which may indicate a governmental interest in adopting a more comprehensive regulatory framework for SUD reprocessing. To date, AMDR is unaware of either third-party reprocessing taking place in KSA or importation of third-party reprocessed devices into KSA.

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<sup>25</sup> [Consumer Information Regarding Single-Use Medical Devices](#), Saudi Food and Drug Authority (visited 07/11/11).

<sup>26</sup> *Id.*